

TAVR for Bicuspid Aortic Valve

Sung-Han Yoon, MD

Cedars-Sinai Heart Institute, Los Angeles, California



Disclosure Statement of Financial Interest

Sung-Han Yoon, MD

Within the past 12 months, I or my spouse/partner have had no financial interest/arrangement or affiliation with any organization(s).

Background

- TAVR indication is expanding into a lower-risk population
- The prevalence of bicuspid aortic valve is higher in a younger population
- Bicuspid AS has been excluded from randomized trials
- There is limited data assessing the outcomes of TAVR in Bicuspid AS

Background

Recent Published study

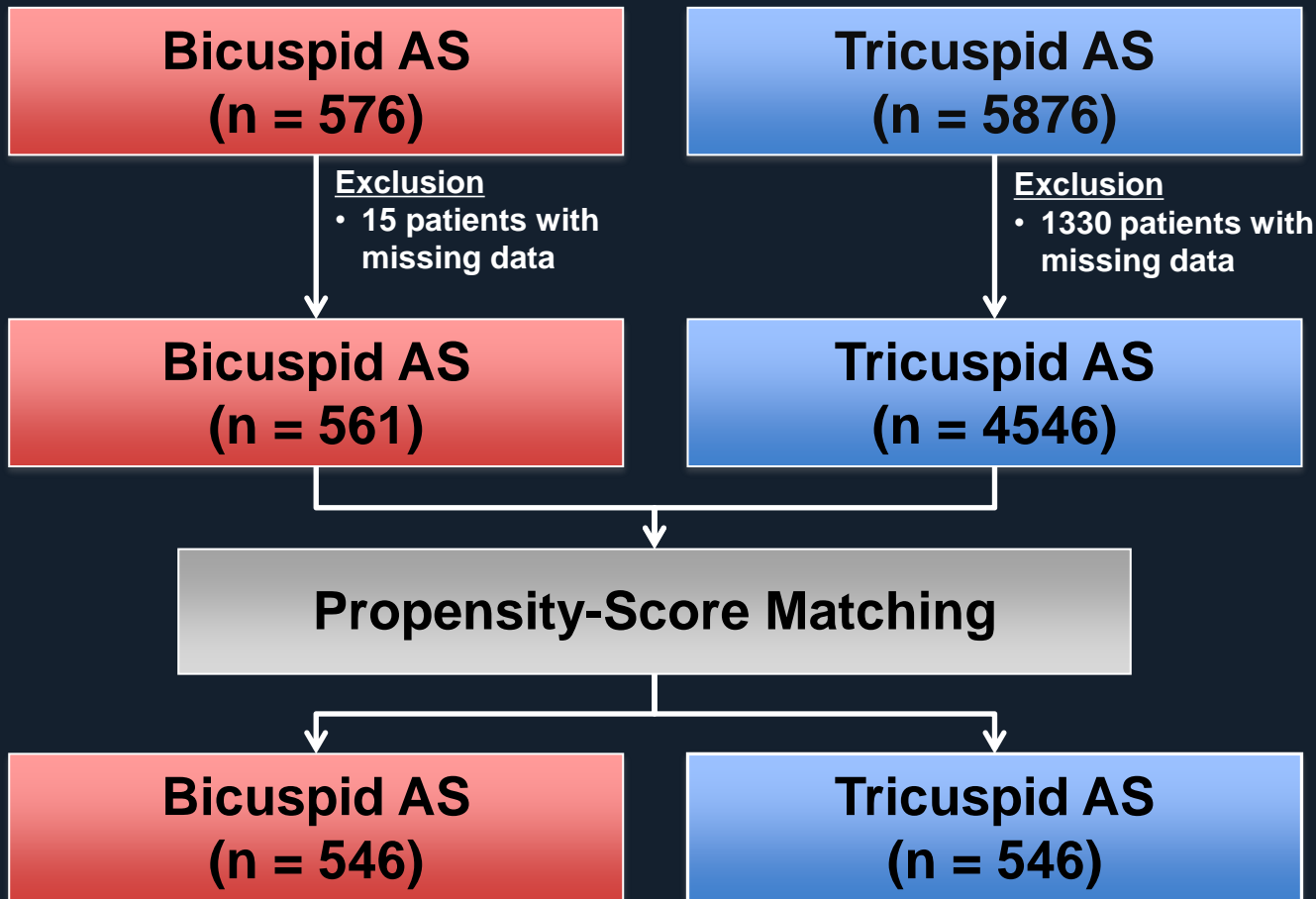
ORIGINAL INVESTIGATIONS

Outcomes in Transcatheter Aortic Valve Replacement for Bicuspid Versus Tricuspid Aortic Valve Stenosis



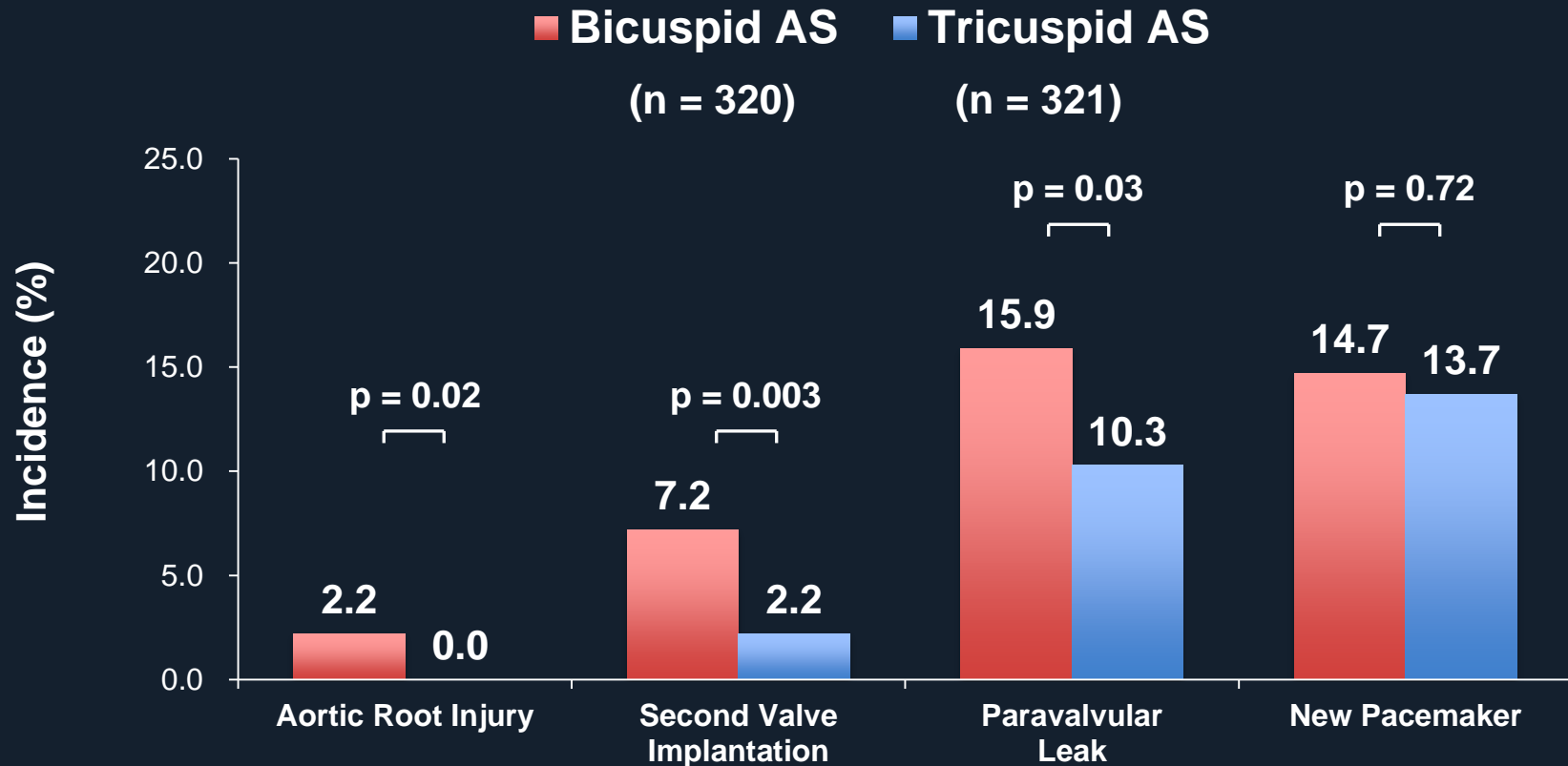
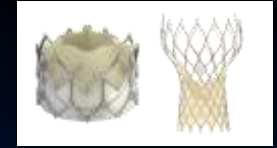
Sung-Han Yoon, MD,^a Sabine Bleiziffer, MD,^b Ole De Backer, MD,^c Victoria Delgado, MD,^d Takahide Arai, MD,^e Johannes Ziegelmüller, MD,^b Marco Barbanti, MD,^f Rahul Sharma, MD,^g Gidon Y. Perlman, MD,^h Omar K. Khalique, MD,^b Erik W. Holy, MD,ⁱ Smriti Saraf, MD,^j Florian Deuschl, MD,^k Buntaro Fujita, MD,^l Philipp Ruile, MD,^m Franz-Josef Neumann, MD,ⁿ Gregor Pache, MD,^o Masao Takahashi, MD,^o Hidehiro Kaneko, MD,^o Tobias Schmidt, MD,^q Yohei Ohno, MD,^r Niklas Schofer, MD,^s William K.F. Kong, MD,^{t,u} Edgar Tay, MD,^v Daisuke Sugiyama, MD,^w Hiroyuki Kawamori, MD,^x Yoshio Maeno, MD,^x Yigal Abramowitz, MD,^y Tarun Chakravarty, MD,^z Mamoo Nakamura, MD,^z Shingo Kuwata, MD,¹ Gerald Yong, MD,² Hsien-Li Kao, MD,³ Michael Lee, MD,⁴ Hyo-Soo Kim, MD,⁵ Thomas Modine, MD,⁶ S. Chiu Wong, MD,⁷ Francesco Bedgoni, MD,⁸ Luca Testa, MD,⁹ Emmanuel Teiger, MD,¹⁰ Christian Butter, MD,¹¹ Stephan M. Ensminger, MD,¹² Ulrich Schaefer, MD,¹³ Danny Dvir, MD,¹⁴ Philipp Blanke, MD,¹⁵ Jonathon Leipsic, MD,¹⁶ Fabian Nietlispach, MD,¹⁷ Mohamed Abdel-Wahab, MD,¹⁸ Bernard Chevalier, MD,¹⁹ Corrado Tamburino, MD,²⁰ David Hildick-Smith, MD,²¹ Brian K. Whisenant, MD,²² Seung-Jung Park, MD,²³ Antonio Colombo, MD,²⁴ Azeem Latib, MD,²⁵ Susheel K. Kodali, MD,²⁶ Jeroen J. Bax, MD,²⁷ Lars Søndergaard, MD,²⁸ John G. Webb, MD,²⁹ Thierry Lefèvre, MD,³⁰ Martin B. Leon, MD,³¹ Raj Makkar, MD³²

Study Design



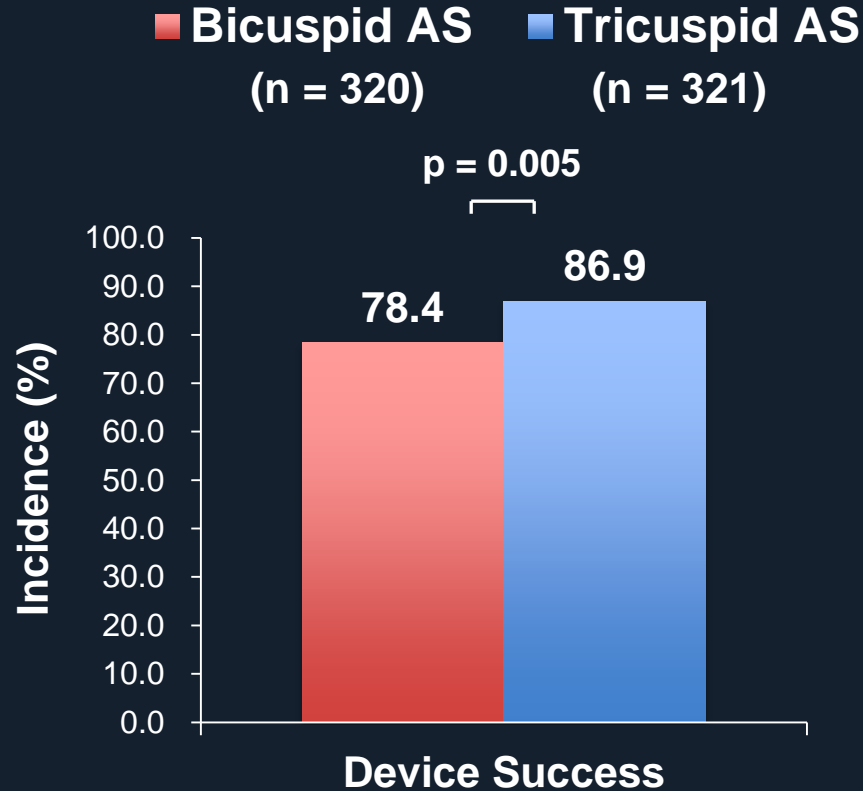
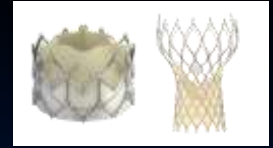
Procedural Outcomes

Early Generation Devices



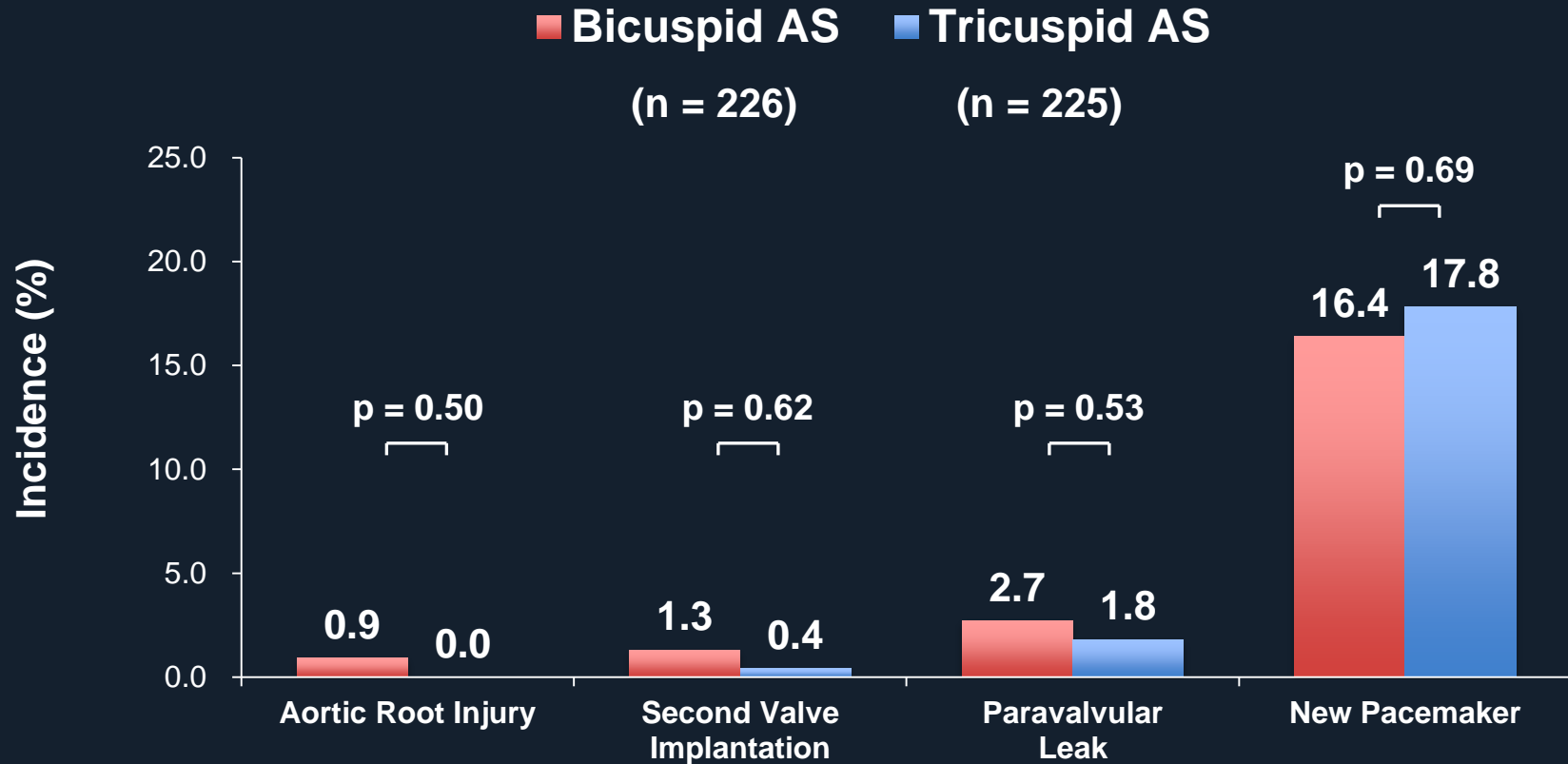
Procedural Outcomes

Early Generation Devices



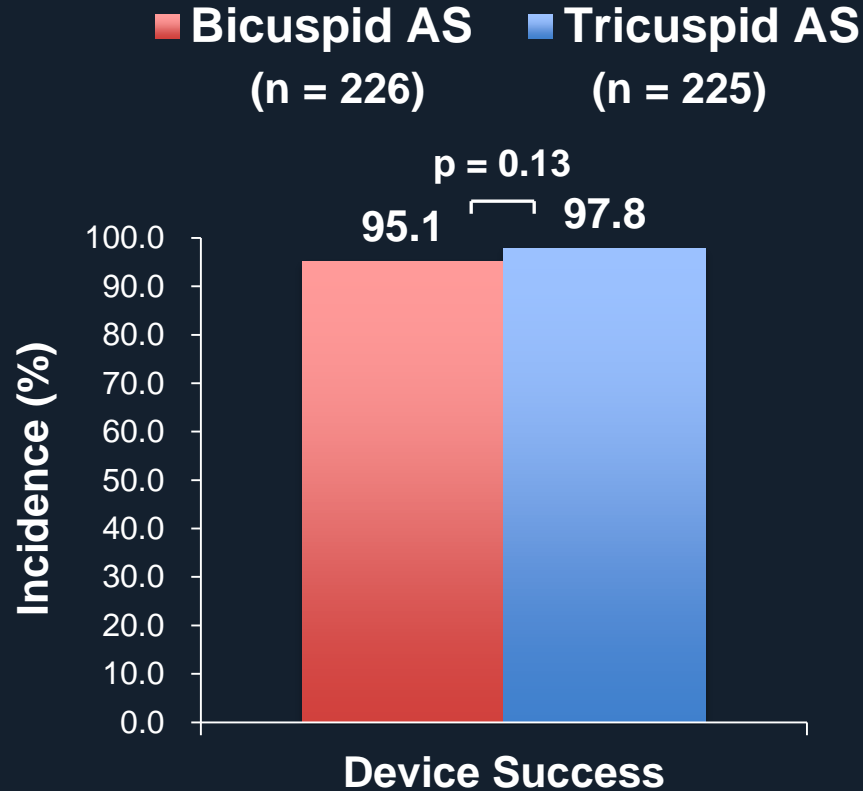
Procedural Outcomes

New Generation Devices



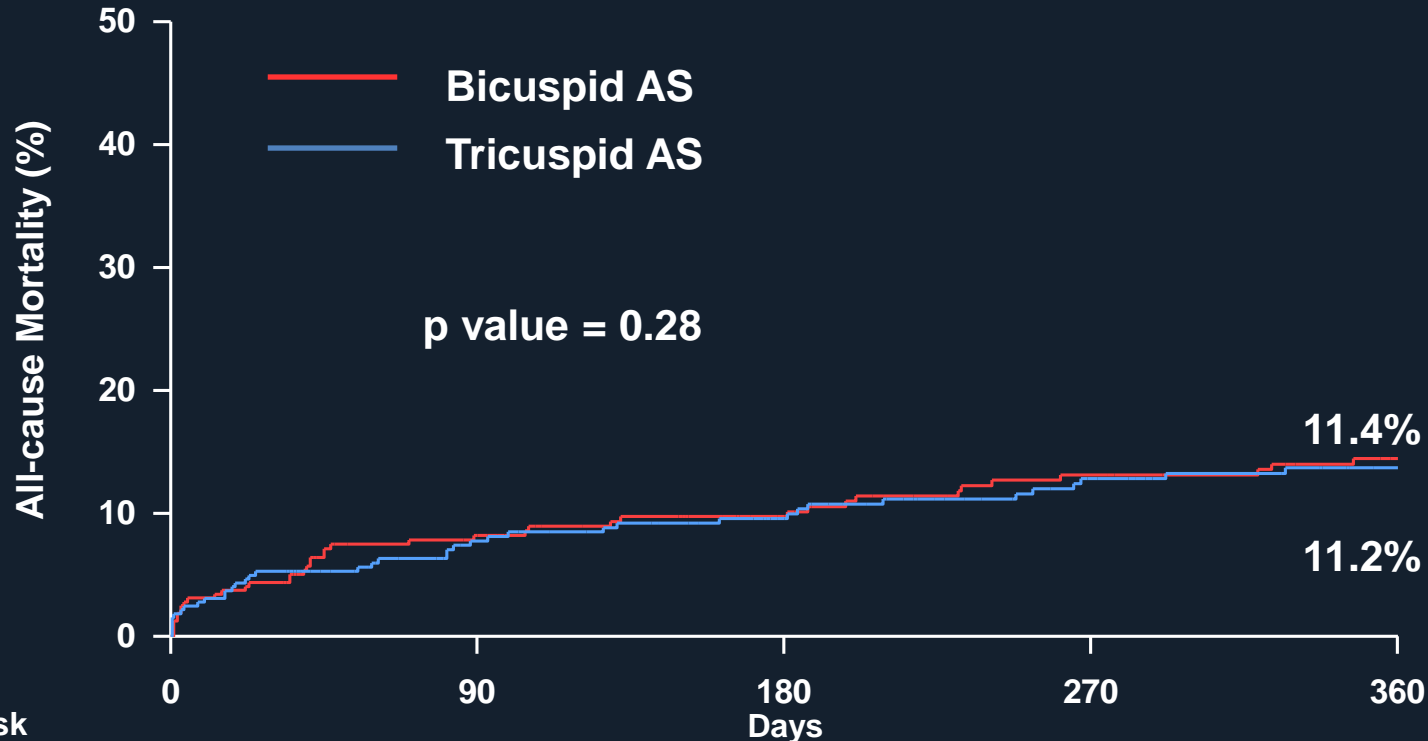
Procedural Outcomes

New Generation Devices



1-year All-cause Mortality

Overall Propensity Matched Cohort



No. at Risk

Bicuspid AS 546

Tricuspid AS 546

308

379

235

280

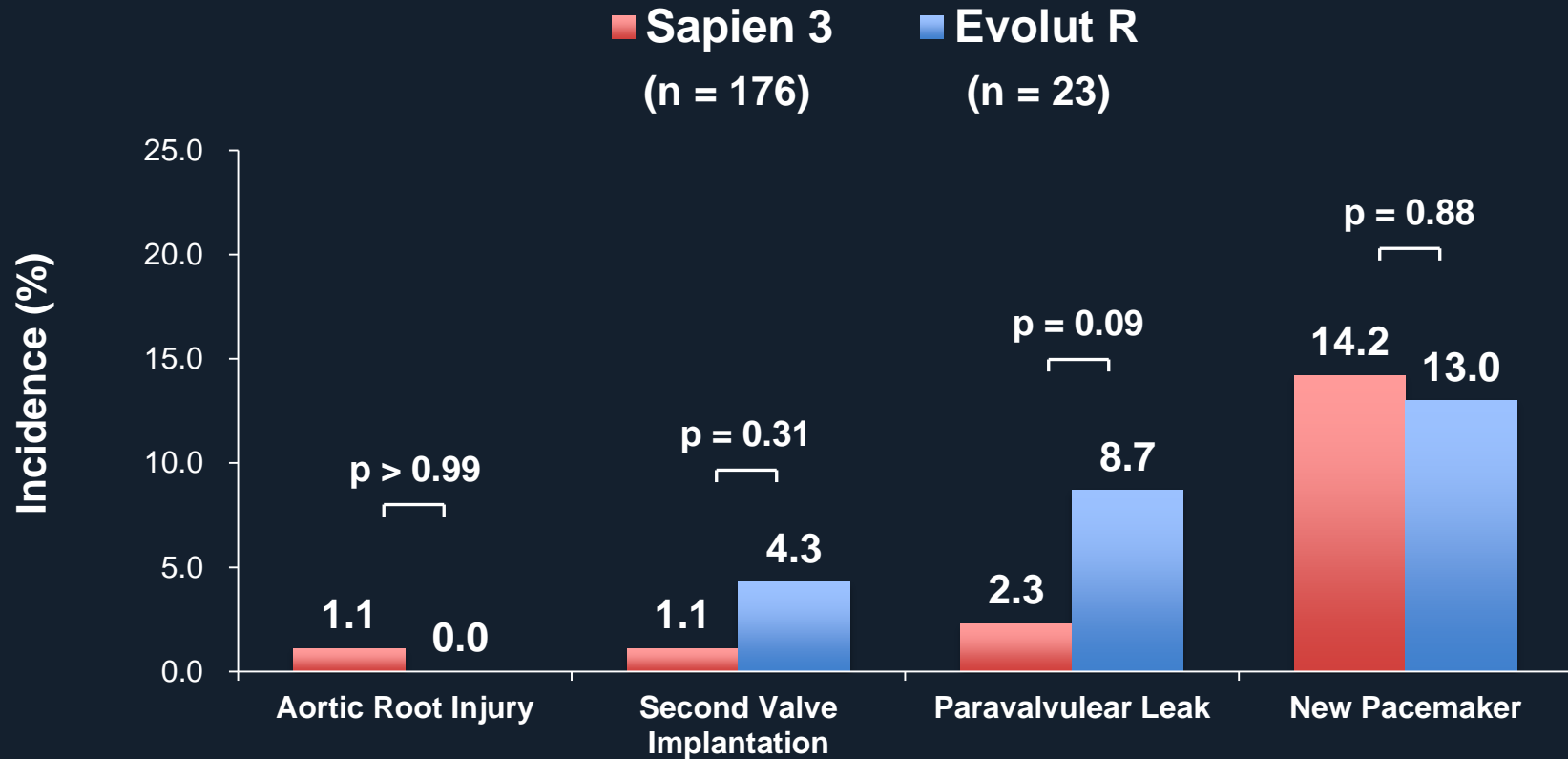
Summary

- Among patients receiving **early generation devices**, bicuspid AS had more frequent ***aortic root injury*** and moderate-severe ***paravalvular leak***
- Among patients receiving **new generation devices**, procedural outcomes were similar between bicuspid and tricuspid AS
- **All-cause mortality rates at 1-year** were similar between bicuspid and tricuspid AS

Outcomes According to Device Type

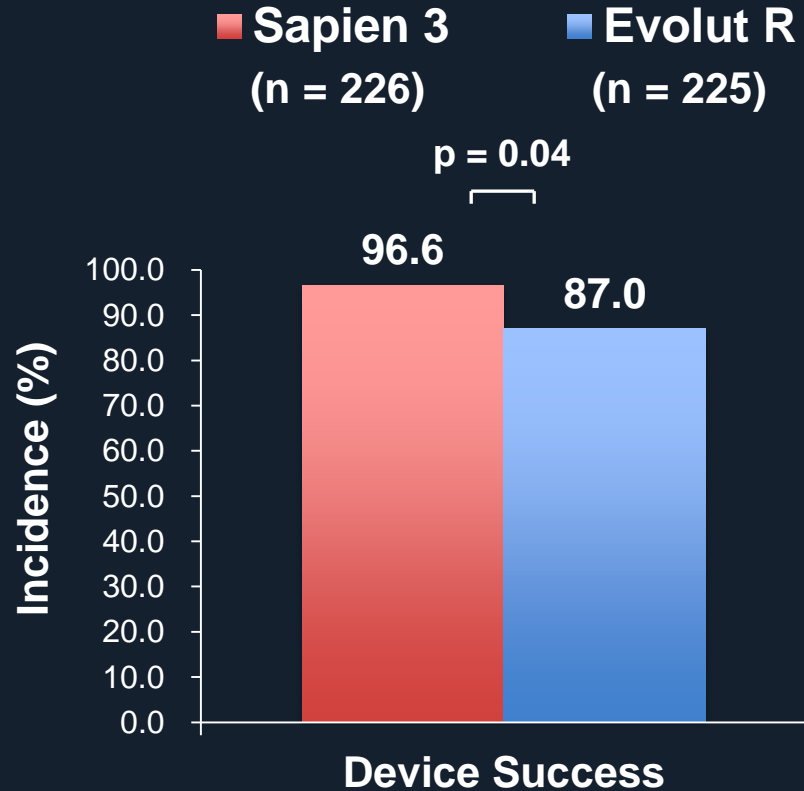
Procedural Outcomes

Sapien 3 vs Evolut R



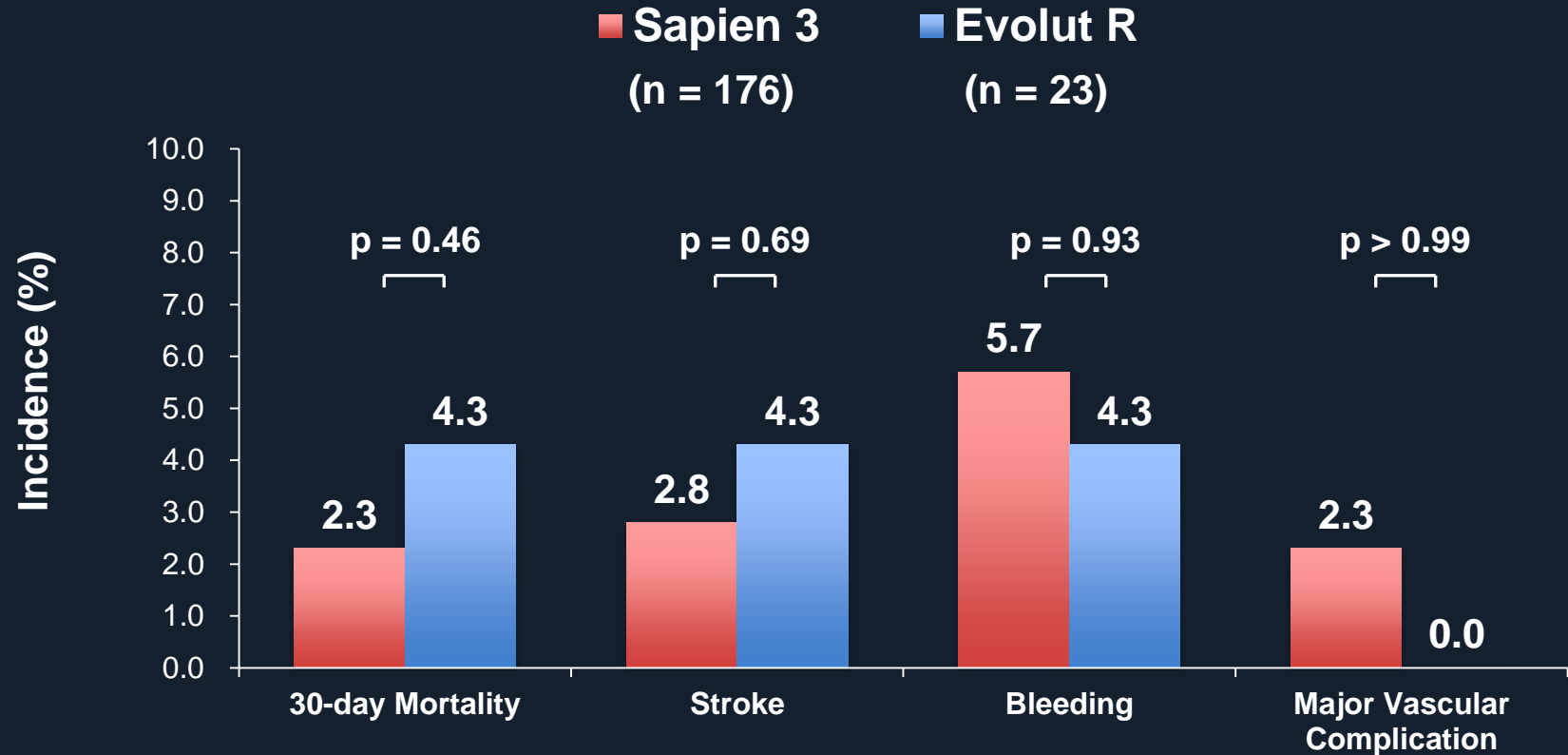
Procedural Outcomes

New Generation Devices

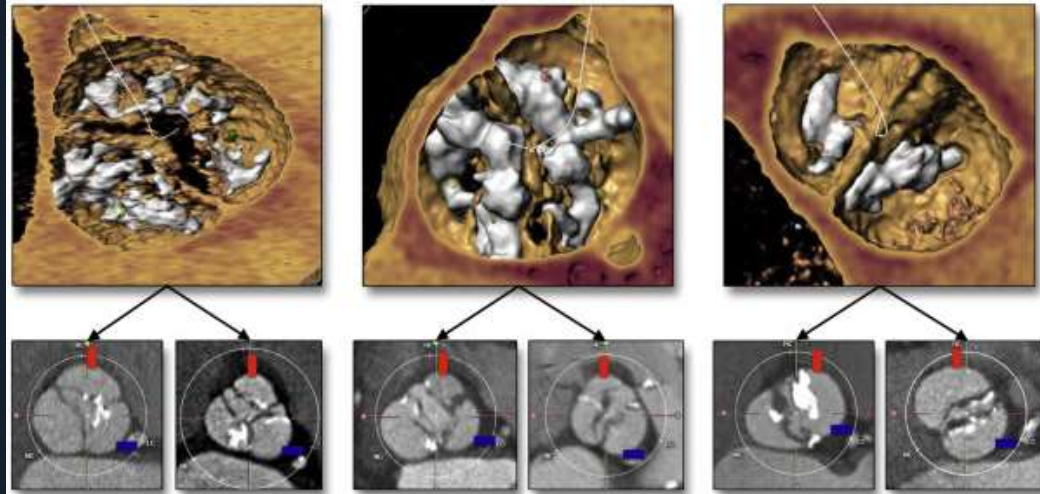


Clinical Outcomes

Sapien 3 vs Evolut R



Bicuspid AV Morphology



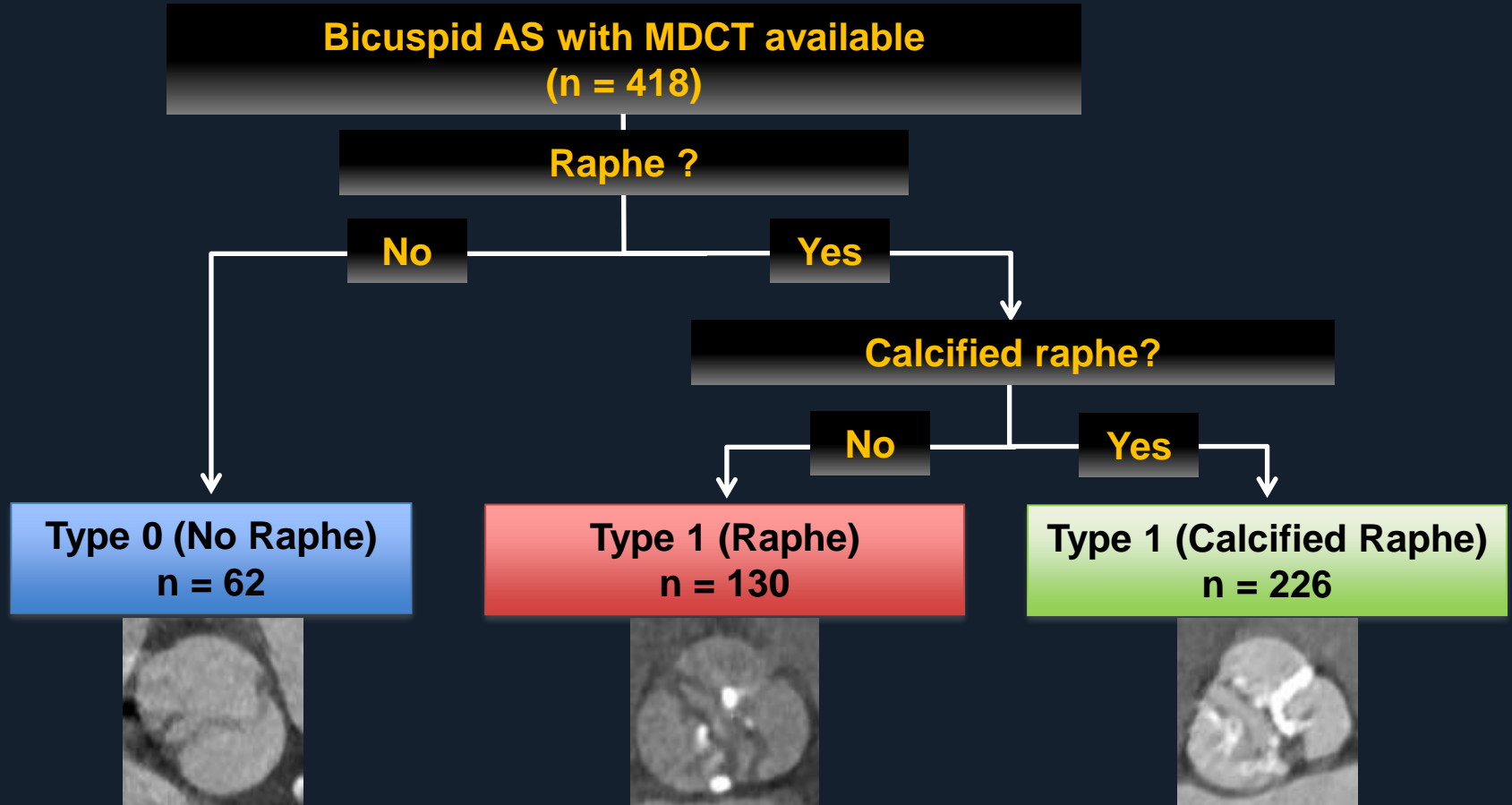
Hasan Jilaihawi et al; JACC: Cardiovascular Imaging, Volume 9, Issue 10, 2016, 1145–1158

Limited data exists about the impact of bicuspid morphology and outcomes of TAVR

Methods

- The Bicuspid AS TAVR multicenter registry was used to evaluate procedural and clinical outcomes
- Bicuspid aortic valve morphology was defined by independent analysis of computed tomography images
- Procedural and clinical outcomes were assessed according to VARC-2 criteria

Study Design



Baseline Characteristics

Demographics

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Age, years	75 ± 8	77 ± 9	76 ± 9	0.18
Male	65%	56%	66%	0.15
NYHA class III / IV	69%	80%	79%	0.24
LVEF, %	50.9 ± 16.1	54.1 ± 15.4	50.8 ± 15.9	0.15
Mean gradient, mm Hg	26.9 ± 15.8	26.2 ± 15.6	28.2 ± 16.2	0.44
STS score, %	4.5 ± 5.6	4.1 ± 3.2	5.2 ± 5.3	0.09
Logistic EuroSCORE, %	12.7 ± 11.8	15.4 ± 11.1	14.3 ± 12.3	0.50

Baseline Characteristics

Demographics

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Diabetes mellitus	24%	22%	24%	0.95
Hypertension	65%	56%	66%	0.63
COPD	21%	24%	20%	0.68
PVD	21%	19%	13%	0.23
Prior PCI	16%	19%	21%	0.67
Prior CABG	15%	12%	11%	0.70
Prior CVA	19%	14%	17%	0.59

Baseline Characteristics

Procedure

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Transfemoral access	81%	88%	89%	0.18
Device				
Early generation devices	69%	50%	53%	0.03
CoreValve	47%	19%	24%	< 0.001
Sapien XT	23%	32%	29%	0.44
New generation devices	31%	50%	47%	0.03
Sapien 3	23%	40%	38%	0.05
Lotus	8%	7%	5%	0.55
Evolut R	0%	3%	4%	0.23

Procedural Outcomes

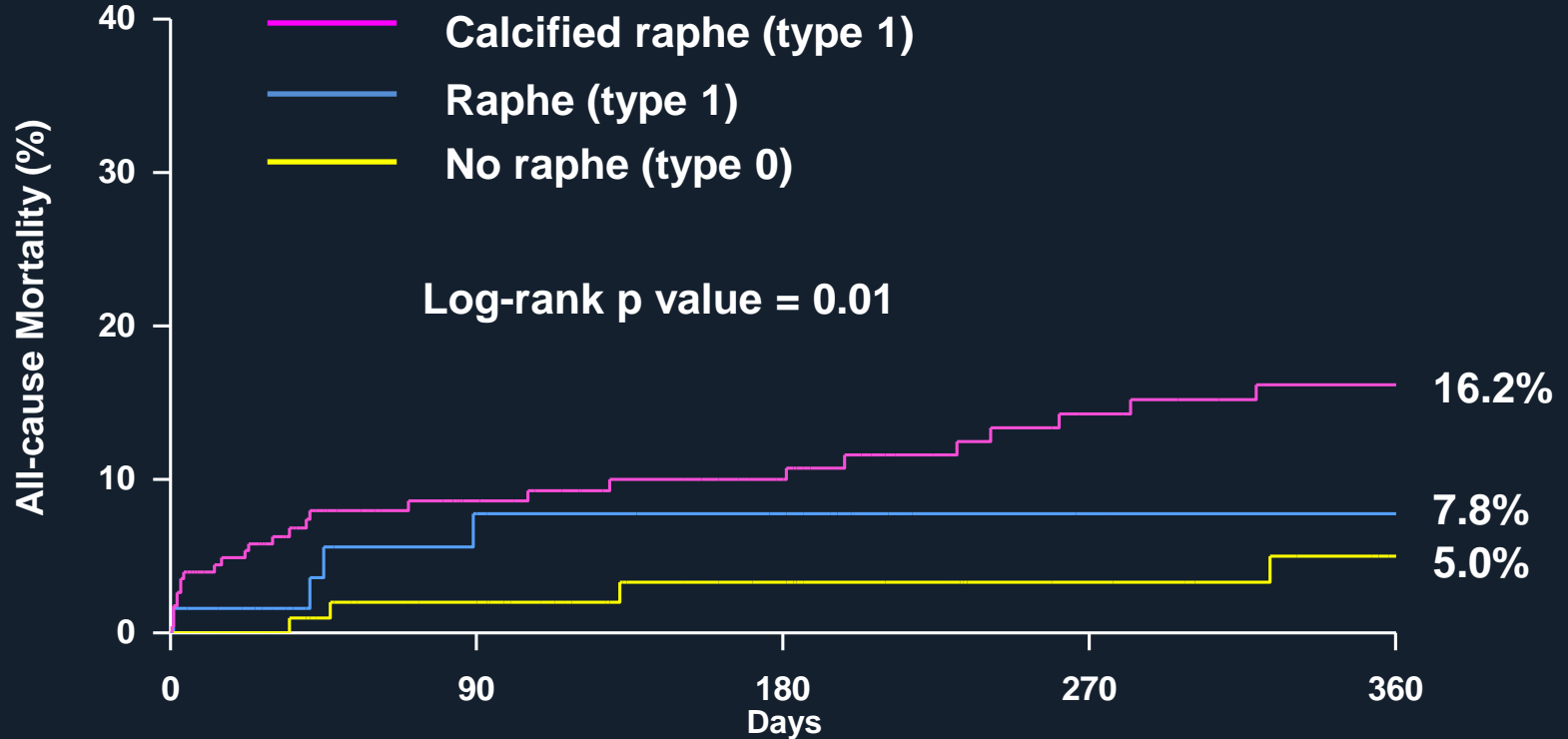
	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
Device success	87.1%	90.8%	83.6%	0.17
Second valve implantation	6.5%	1.5%	5.8%	0.14
Conversion to surgery	1.6%	1.5%	2.7%	0.89
Coronary obstruction	3.2%	0.8%	0.9%	0.29
New permanent pacemaker	11.3%	16.2%	19.0%	0.34
PVL ≥ moderate	6.5%	7.7%	11.1%	0.40
Annulus rupture	0.0%	0.8%	2.7%	0.36
Procedural mortality	1.6%	0.0%	2.7%	0.17

30-day Clinical Outcomes

	Type 0 No raphe (n = 62)	Type 1 Raphe (n = 130)	Type 1 Calcified Raphe (n = 72)	P value
30-day mortality	1.6%	0.0%	6.2%	0.003
Stroke	0.0%	3.1%	2.2%	0.52
Life-threatening bleeding	0.0%	0.0%	2.7%	0.13
Major vascular complication	0.0%	2.3%	4.9%	0.15
AKI (stage 2 or 3)	1.6%	2.3%	1.8%	0.89

1-year All-cause Mortality

Overall Cohort

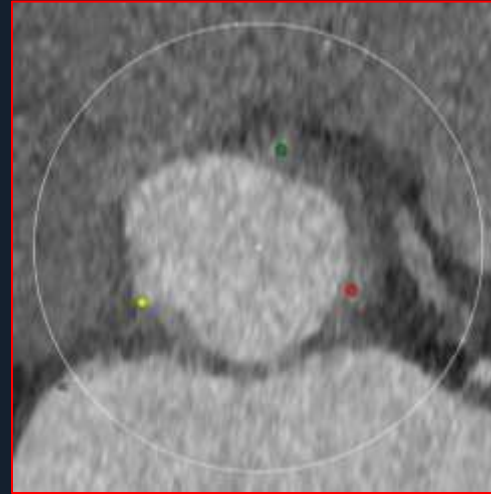


Case Presentation 1

Case 1 – Type 1 (Raphe)



Raphe in LR



Annulus Area: **445 mm²**
Annulus Perimeter: **76 mm**
Max Diameter: **25.8 mm**
Min Diameter: **21.7 mm**

Device Sizing Chart

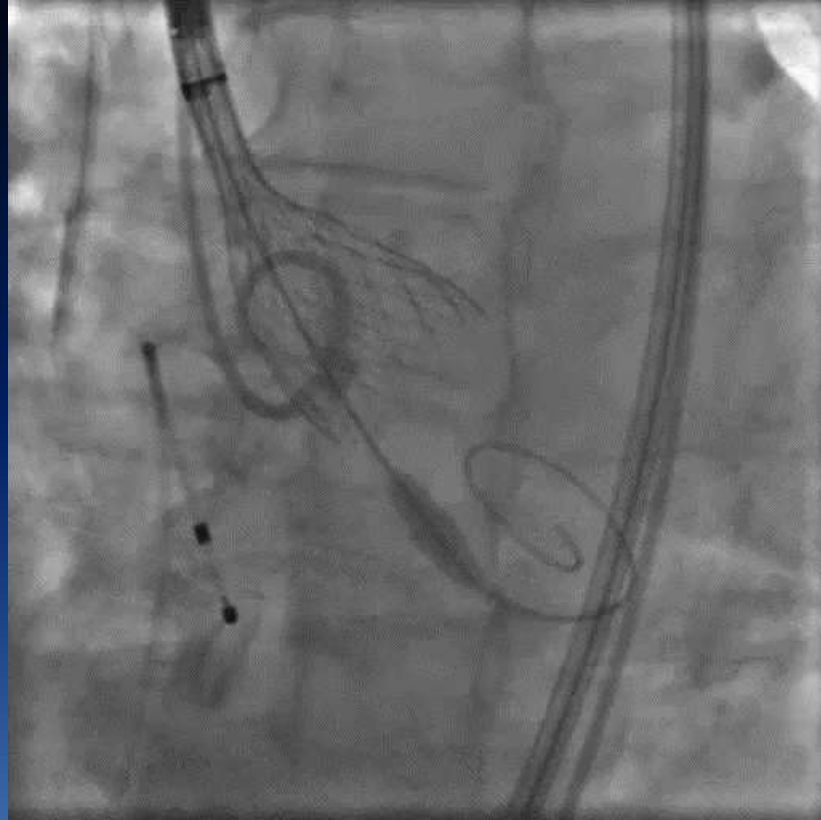
Evolut R

Valve size , mm	23	26	29	34
Annulus Diameter, mm	18 - 20	20 - 23	23 - 26	26 – 30
Annulus Perimeter, mm	56.5 - 62.8	62.8 - 72.3	72.3-81.7	81.7 - 94.2
SOV diameter (mean), mm	≥ 25	≥ 27	≥ 29	≥ 31
SOV height, mm	≥ 15	≥ 15	≥ 15	≥ 16
Sheath Size (OD)	14 F	14 F	14 F	16 F
Min Vessel Diameter, mm	5	5	5	5.5

Case 1 – Type 1 (Raphe)



Case 1 – Type 1 (Raphe)



Case 1 – Type 1 (Raphe)



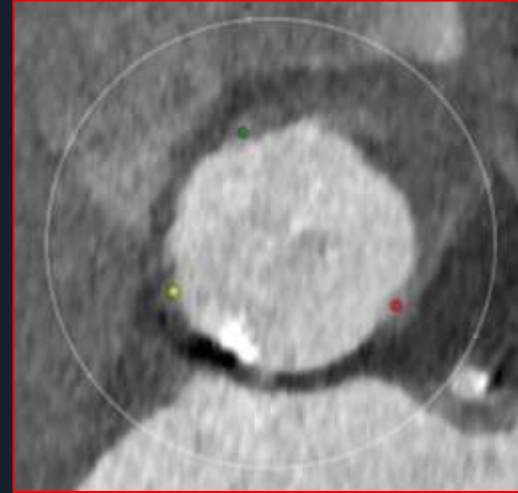
None – trivial PVL, No need for PPM

Case Presentation 2

Case 2 – Type 1 (Calcified raphe)



Calcified raphe in NR



Annulus Area: **594 mm²**
Annulus Perimeter: **87 mm**
Max Diameter: **27.8 mm**
Min Diameter: **27.2 mm**

Device Sizing Chart

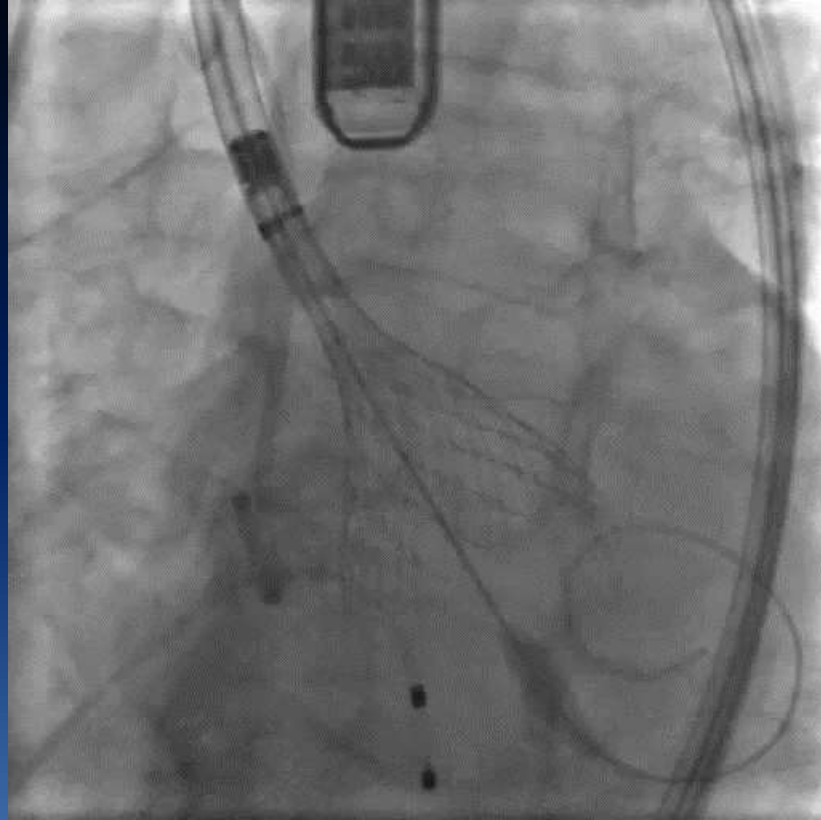
Evolut R

Valve size , mm	23	26	29	34
Annulus Diameter, mm	18 - 20	20 - 23	23 - 26	26 – 30
Annulus Perimeter, mm	56.5 - 62.8	62.8 - 72.3	72.3-81.7	81.7 - 94.2
SOV diameter (mean), mm	≥ 25	≥ 27	≥ 29	≥ 31
SOV height, mm	≥ 15	≥ 15	≥ 15	≥ 16
Sheath Size (OD)	14 F	14 F	14 F	16 F
Min Vessel Diameter, mm	5	5	5	5.5

Case 2 – Type 1 (Calcified raphe)



Case 2 – Type 1 (Calcified raphe)



Case 2 – Type 1 (Calcified raphe)



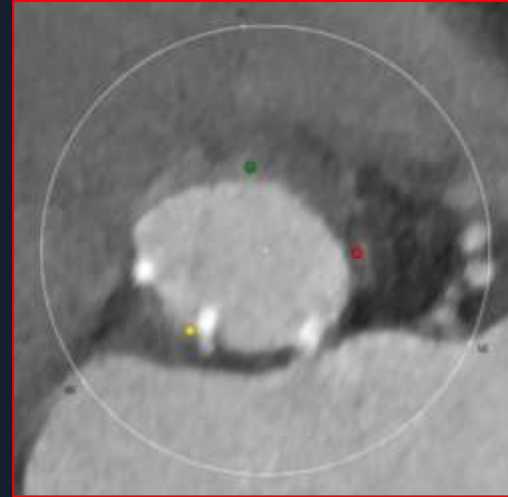
Mild PVL, No Need for PPM

Case Presentation 3

Case 3 – Type 1 (Calcified raphe)



Type 1 (Calcified Raphe)



Annulus Area: 369 mm²
Annulus Perimeter: 70 mm
Max Diameter: 25.9 mm
Min Diameter: 17.8 mm

Device Sizing Chart

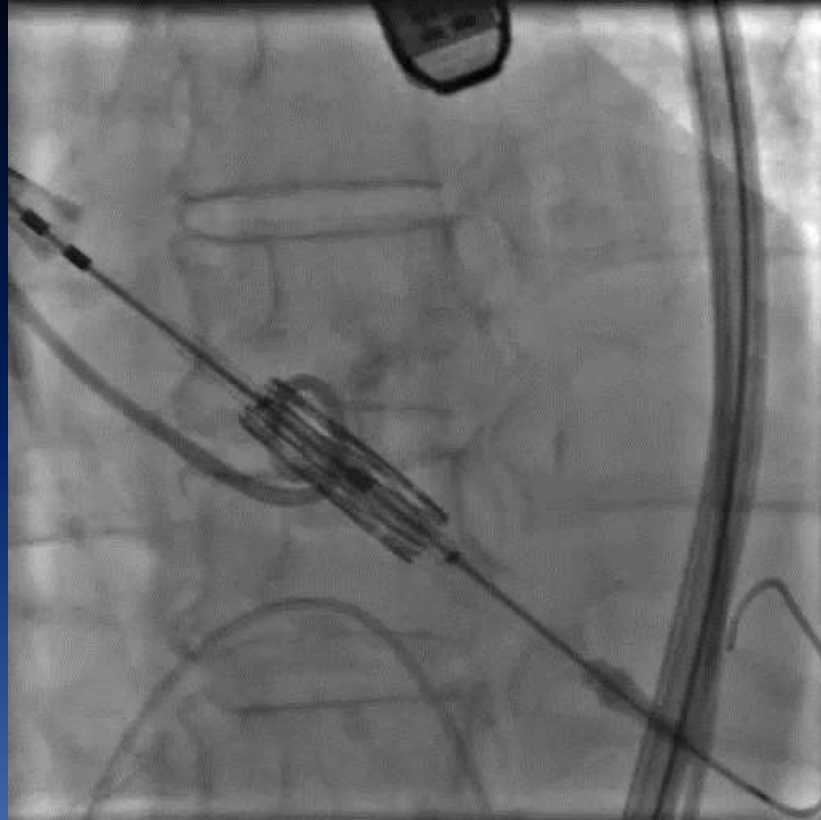
SAPIEN 3

Valve size , mm	20	23	26	29
Nominal area, mm ²	328	409	519	649
Device height, mm	15.5	18	20	22.5
Annulus Area, mm ²	273 - 345	338 – 430	430 – 546	540 – 683
Area-derived diameter, mm	18.6 - 21.0	20.7 - 23.4	23.4 - 26.4	26.2 - 29.5
Sheath Size (OD)	14 F	14 F	14 F	16 F
Min Vessel Diameter, mm	5.5	5.5	5.5	6.0

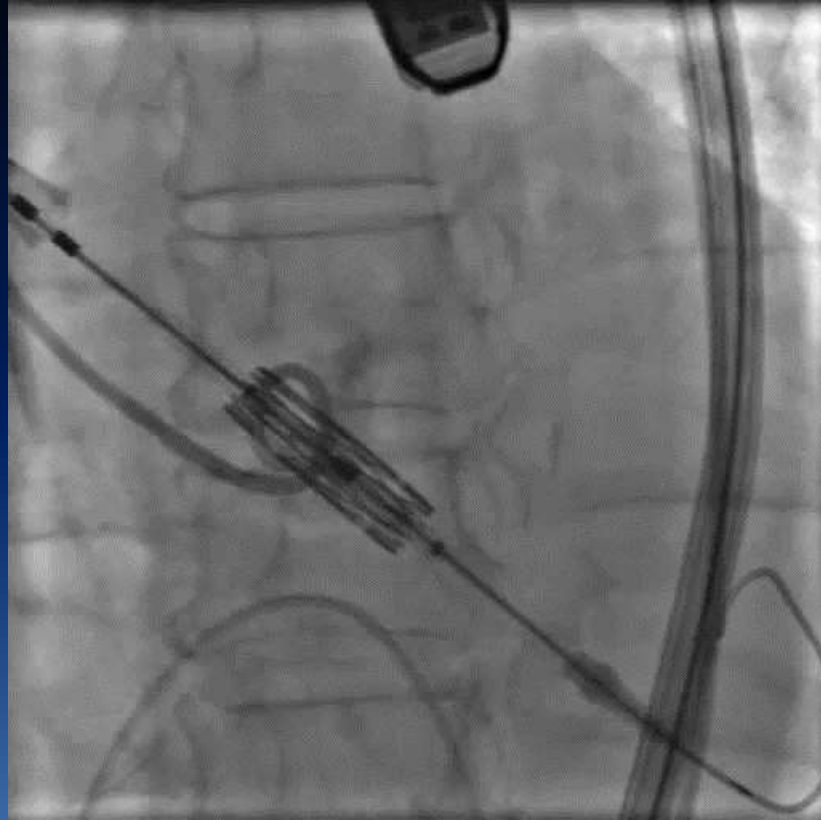
Case 3 – Type 1 (Calcified raphe)



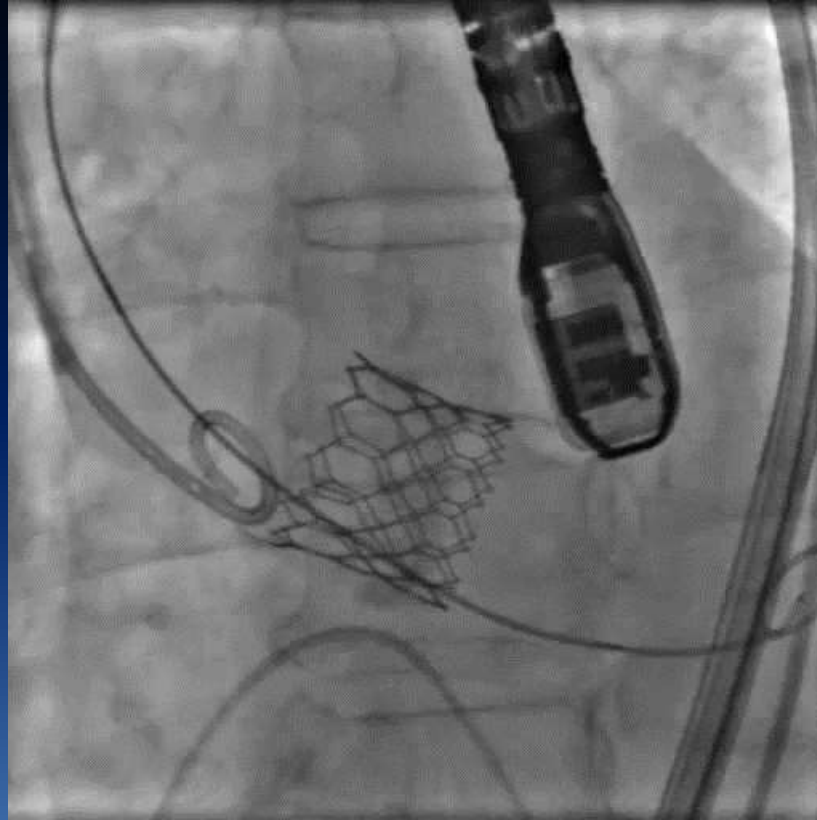
Case 3 – Type 1 (Calcified raphe)



Case 3 – Type 1 (Calcified raphe)



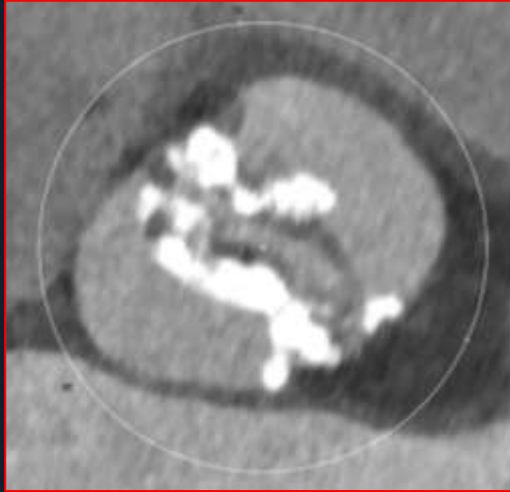
Case 3 – Type 1 (Calcified raphe)



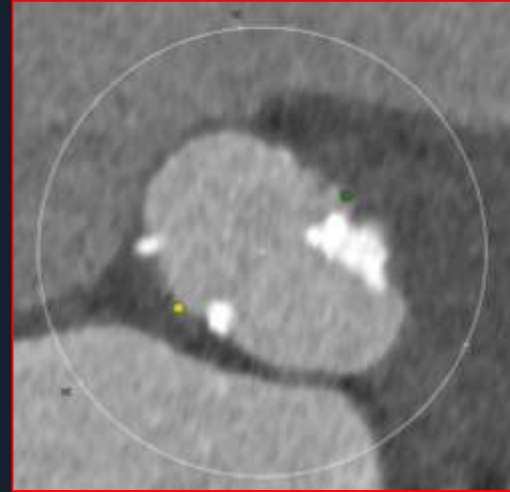
Mild PVL

Case Presentation 4

Case 4 – Type 0 (No raphe)



Type 0 (No Raphe)



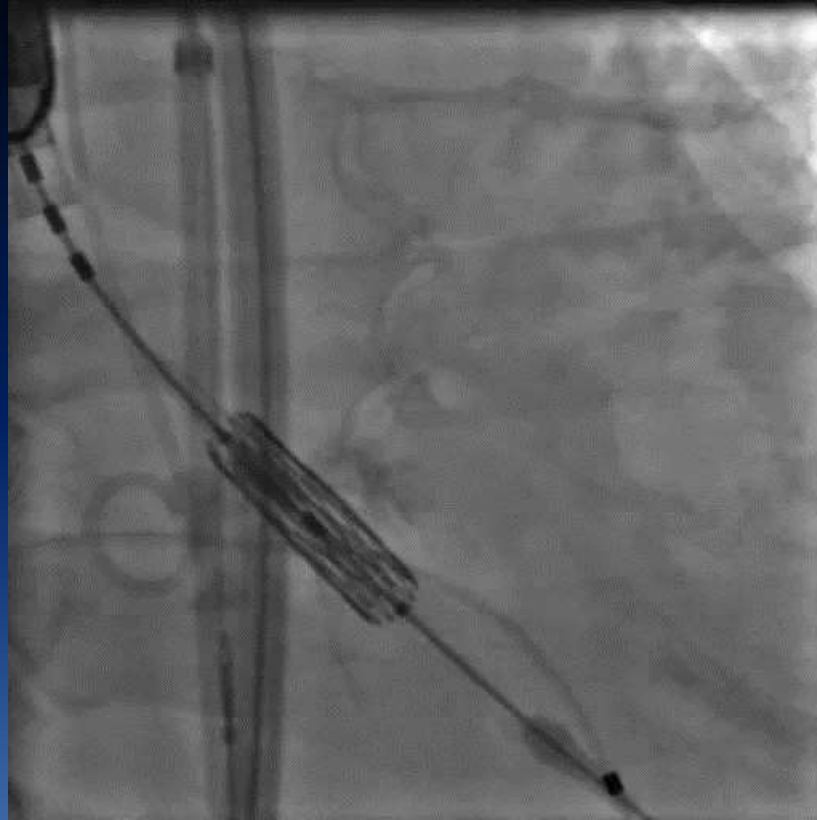
Annulus Area: 563 mm²
Annulus Perimeter: 87 mm
Max Diameter: 33.0 mm
Min Diameter: 21.5 mm

Device Sizing Chart

SAPIEN 3

Valve size , mm	20	23	26	29
Nominal area, mm ²	328	409	519	649
Device height, mm	15.5	18	20	22.5
Annulus Area, mm ²	273 - 345	338 – 430	430 – 546	540 – 683
Area-derived diameter, mm	18.6 - 21.0	20.7 - 23.4	23.4 - 26.4	26.2 - 29.5
Sheath Size (OD)	14 F	14 F	14 F	16 F
Min Vessel Diameter, mm	5.5	5.5	5.5	6.0

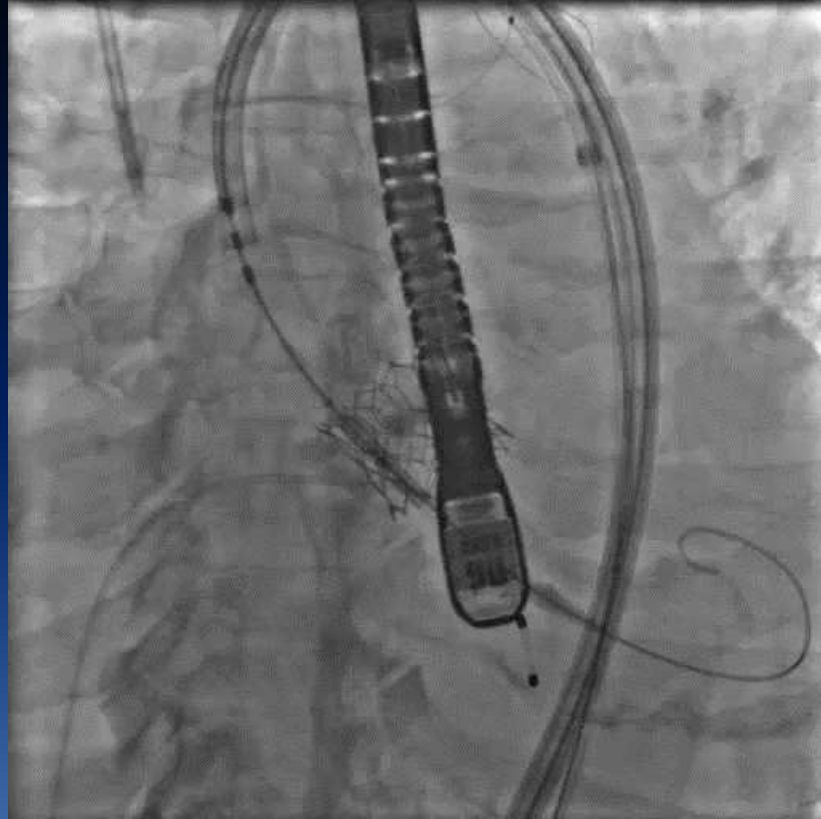
Case 4 – Type 0 (No raphe)



Case 4 – Type 0 (No raphe)



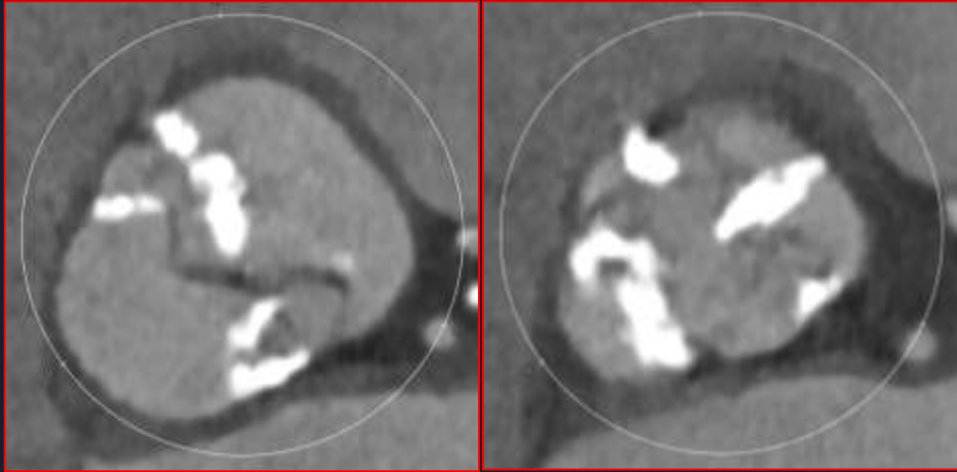
Case 4 – Type 0 (No raphe)



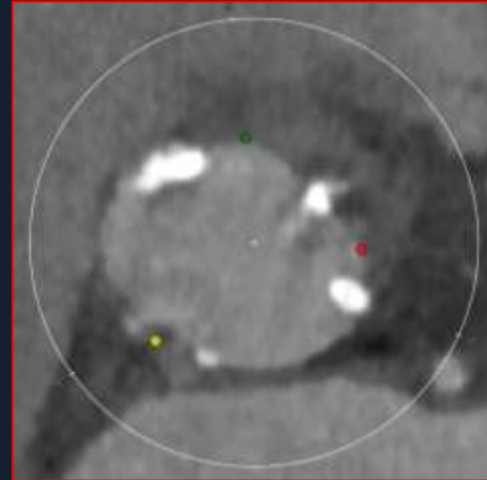
Mild PVL

Case Presentation 5

Case 5 – Type 1 (Calcified raphe)

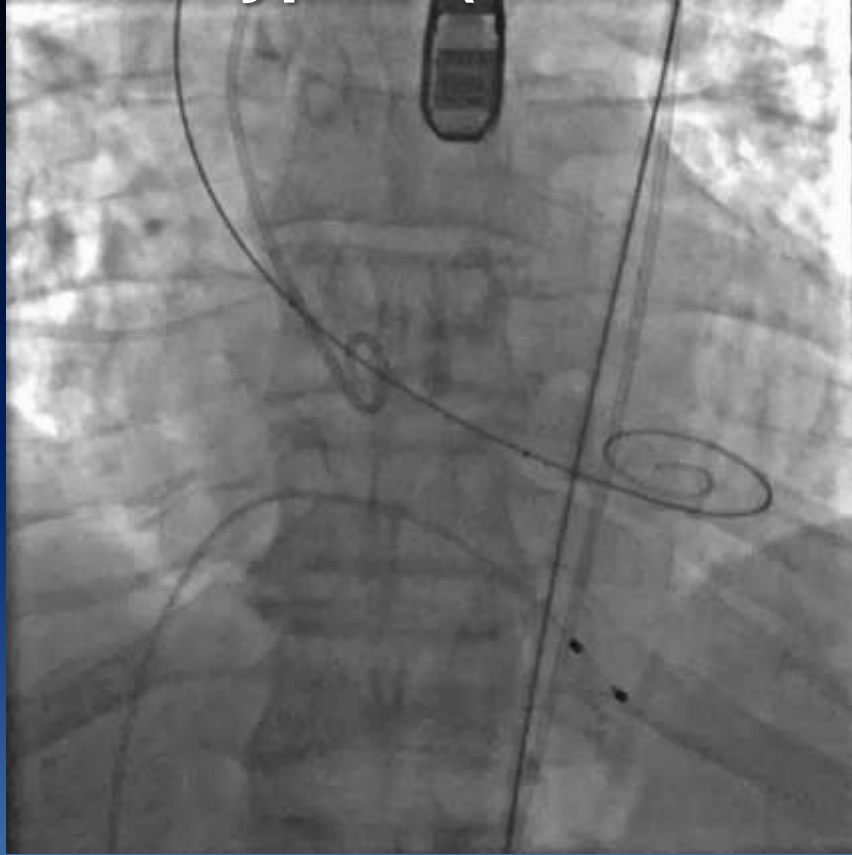


Calcified raphe in LR



Annulus Area: **551 mm²**
Annulus Perimeter: **84 mm**
Max Diameter: **29.9 mm**
Min Diameter: **23.9 mm**

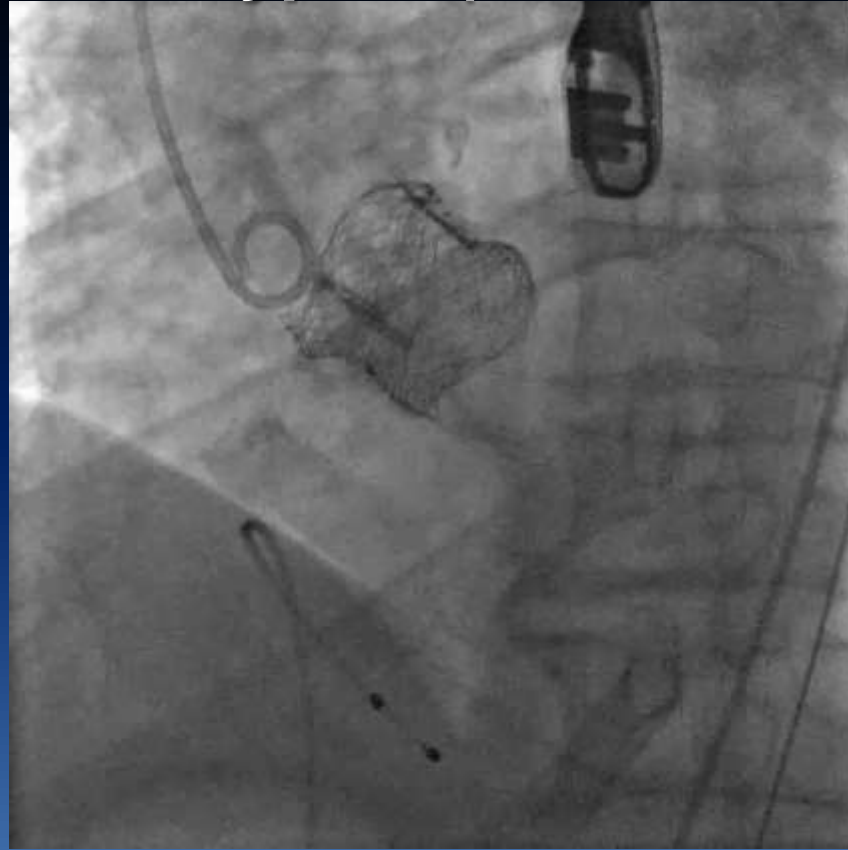
Case 5 – Type 1 (Calcified raphe)



Case 5 – Type 1 (Calcified raphe)



Case 5 – Type 1 (Calcified raphe)



No PVL, No need for PPM

Conclusions

- TAVR for bicuspid AS was feasible and safe
- When using early-generation devices, TAVR for bicuspid AS was associated with more frequent procedural complications
- However, when using new-generation devices, outcomes of TAVR for bicuspid were similar to those of tricuspid AS

Conclusions

- TAVR for **type 0 bicuspid AS** was preferable
- TAVR for **type 1 bicuspid AS with calcified raphe** was challenging
 - New-generation balloon-expandable and self-expanding valves can be applied
 - **Intentional down sizing** may be considered to avoid catastrophic complications